In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

Petitioners,

JEFFREY SEARS and BRITTNEY * No. 21-1651V

SEARS, parents of G.S., a minor,

* Special Master Christian J. Moran

Filed: July 12, 2024

SECRETARY OF HEALTH AND HUMAN SERVICES,

v.

*

Respondent.

Ronald Craig Homer and Christina Ciampolillo, Conway, Homer, P.C., Boston, MA, for petitioner;

Rachelle Bishop, United States Dep't of Justice, Washington, DC, for respondent.

<u>UNPUBLISHED DECISION DENYING COMPENSATION</u>¹

Jeffrey and Brittney Sears ("petitioners") alleged that the hepatitis B vaccine and/or inactive polio vaccine their child G.S. received on August 7, 2019 caused G.S. to suffer from alopecia areata. On June 28, 2024, petitioners moved for a decision dismissing their petition.

I. Procedural History

Petitioners filed a petition for compensation on August 2, 2021, alleging that the hepatitis B vaccine and/or inactive polio vaccine their daughter G.S. received

¹ Because this decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). This means the decision will be available to anyone with access to the internet. In accordance with Vaccine Rule 18(b), the parties have 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. Any changes will appear in the document posted on the website.

on August 7, 2019 caused her to suffer alopecia areata the next day. Pet. at 1-2. They filed medical records and affidavits over the next few months.

The Secretary filed his Rule 4(c) report on May 25, 2022, contesting entitlement. The Secretary argued that petitioners had not provided preponderant evidence of a causal connection between G.S.'s condition and either of the vaccines. Resp't's Rep. at 10. Further, the Secretary noted that petitioners had not submitted an expert report in support of their claim, and that none of G.S.'s treating doctors opined that the vaccines caused her alopecia areata. <u>Id.</u>

On November 18, 2022, petitioners filed an expert report from Dr. Richard Horan, a dermatologist with training in immunology. Exhibit 17. Dr. Horan opined that the hepatitis B vaccination caused G.S.'s alopecia areata via molecular mimicry, and that the onset was within an appropriate timeframe. <u>Id.</u> at 3-4. Dr. Horan cited three articles associating the hepatitis vaccine with alopecia areata. <u>Id.</u> at 3.

The Secretary submitted reports from dermatologist Andrew Krakowski and immunologist Andrew MacGinnitie in response. Dr. Krakowski cited an epidemiologic study that did not detect an increased incidence of alopecia areata after the hepatitis B vaccine. Exhibit A at 11. He opined that the onset of 36 hours post-vaccination was too fast, and proposed alternative causes for G.S.'s alopecia areata, including atopic dermatitis, stress from moving across the country, and an infection. <u>Id.</u> at 10-12. Dr. MacGinnitie focused upon molecular mimicry, critiquing how Dr. Horan's reliance on that theory did not fit this case. Exhibit C at 4-7. Like Dr. Krakowski, Dr. MacGinnitie opined that the "time course is far too rapid for an adaptive immune response." <u>Id.</u> at 7.

The parties discussed the reports during a status conference on May 11, 2023. The undersigned commented that Dr. Krakowski and Dr. MacGinnitie had raised several strong points that if unrebutted would likely prevent a finding in petitioners' favor. Petitioners were given an opportunity to supplement the record with another report from Dr. Horan, addressing the reports from the Secretary's experts. Order, issued May 11, 2023.

Petitioners moved for and were granted three extensions of time to file their report. Orders, issued July 11, 2023; Aug. 25, 2023; and Oct. 25, 2023. However,

petitioners were unable to obtain a supplemental report, as Dr. Horan was not responsive to communications. Pet'r's Status Rep., filed Nov. 15, 2023.

An Order to Show Cause issued on May 20, 2024. The undersigned tentatively found that petitioners were not entitled to compensation because they had not presented persuasive evidence of how vaccinations can cause alopecia areata, nor that the temporal interval was appropriate. On June 28, 2024, petitioners moved for a decision dismissing their petition.

II. Analysis

To receive compensation under the National Vaccine Injury Compensation Program ("Program"), a petitioner must prove either 1) that the vaccinee suffered a "Table Injury"—i.e., an injury falling within the Vaccine Injury Table—corresponding to one of the vaccinations, or 2) that the vaccinee suffered an injury that was actually caused by a vaccine. See §§ 300aa-13(a)(1)(A) and 300aa-11(c)(1). Under the Act, a petitioner may not be given a Program award based solely on the petitioner's claims alone. Rather, the petition must be supported by either medical records or by the opinion of a competent physician. § 300aa-13(a)(1).

In this case, petitioners filed medical records, affidavits, and an expert report. Nonetheless, petitioners wish to have their claim dismissed and judgment entered against them. Though it was not specified, the undersigned will construe this as a motion filed pursuant to 42 U.S.C. § 300aa-21(b) (regarding involuntary dismissal), given petitioners' clear intent that a judgment issue in this case. <u>See</u> Pet'rs' Mot., filed June 28, 2024 at 2.

To conform to section 12(d)(3), a decision must "include findings of fact and conclusions of law." For causation-in-fact cases, the Federal Circuit has defined elements of a petitioner's claim. Petitioners bear a burden to show by a preponderance of the evidence that the vaccination brought about their injury by providing:

- (1) a medical theory causally connecting the vaccination and the injury;
- (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and
- (3) a showing of a proximate temporal relationship between vaccination and injury.

Althen v. Sec'y of Health & Hum. Servs., 418 F.3d 1274, 1278 (Fed. Cir. 2005).

Petitioners, through Dr. Horan, have presented the theory of molecular mimicry to explain how G.S.'s vaccinations might have caused her condition. Dr. Horan's brief discussion of molecular mimicry is not persuasive. Dr. MacGinnitie persuasively explained why molecular mimicry is an unlikely explanation for how the vaccinations can cause alopecia areata. See Tullio v. Sec'y of Health & Human Servs., No. 15-51V, 2019 WL 7580149, at *13-14 (Fed. Cl. Spec. Mstr. Dec. 19, 2019) (citing cases regarding molecular mimicry), mot. for rev. denied, 149 Fed. Cl. 448, 464-76 (2020).

Furthermore, the process of molecular mimicry takes multiple days, probably at least five days. Contreras v. Sec'y of Health & Human Servs., No. 05-626V, 2012 WL 1441315, at *9-24 (Fed. Cl. Spec. Mstr. April 5, 2012) (lengthy discussion of the time for molecular mimicry), mot. for rev. denied in relevant part after intervening proceedings, 121 Fed. Cl. 230, 246-47 (2015), vacated on other grounds and remanded, 844 F.3d 1363 (Fed. Cir. 2017); Forrest v. Sec'y of Health & Human Servs., No. 14-1046V, 2019 WL 925495, at *3-8 (Fed. Cl. Spec. Mstr. Jan. 28, 2019). Petitioners have not explained how molecular mimicry could cause alopecia areata within 36 hours. Petitioners have therefore not met their burden under Althen.

Thus, the Motion for Decision is GRANTED and this case is DISMISSED WITH PREJUDICE for insufficient proof. The Clerk shall enter judgment accordingly. See Vaccine Rule 21(b).

IT IS SO ORDERED.

s/Christian J. Moran Christian J. Moran Special Master